

## DETAILED ACTION

Applicants' arguments filed June 24, 2009 have been received and entered. Claims 183-186, 189-196, 199-205, 208-210 and 211 are pending in this application.

### *Election/Restrictions*

Applicant's election of Group I drawn to non-human transgenic vertebrate was acknowledged. Claims 183-186, 189-196, 199-205, 208-210 and 211 were drawn to elected subject matter and currently under examination as they are drawn to a non-human transgenic vertebrate.

Claims 212-257 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/9/2004.

Claims 183-186, 189-196, 199-205, 208-210 and 211 are under examination.

### *Priority*

Applicants note that lentiviral vectors are a type of retrovirus that can infect both dividing and non-dividing cells because their pre-integration complex (virus "shell") can get through the intact membrane of the nucleus of the target cell. Applicants point to the disclosure of the '825 application to the support it provides for "a nonhuman mammal whose germ cell comprises viral vector" (page 3 at lines 20-26), extraction of germ cell (page 15, line 11-13) and viruses suitable for use in carrying out the invention including adenoviruses, adeno-associated viruses, retroviruses such human immune-deficiency virus, mumps virus, and transfecting fragments thereof, and other viral DNA segments (page 10, lines 15-23). Applicants note that lentiviral vectors are a type of retrovirus and HIV (human immune deficiency virus) is an example of such a lentiviral vector.

Applicants arguments filed June 24, 2009 have been fully considered but are not persuasive. Applicants argument that lentiviral vectors are a type of retrovirus and HIV (human immune deficiency virus) is an example of such a lentiviral vector (page 26, lines 1-18, the '825 and 34, line 20 - page 35, line 23) provides explicit and implicit descriptive support is not

persuasive. The '825 specification discloses "retrovirus" but this is a very large genus of which "lentivirus" is a type. It should be noted that applicant contemplated HIV, but not all lentiviruses. Additionally, a key factor is the '825 specification contemplated the genus adenovirus, but not lentiviruses. Therefore, there is not adequate support for the claimed use of lentiviral genus in the manner provided by the first paragraph of 35 U.S.C. 112 in '825 applications. Therefore, the effective filing date for instant claims 183-186, 189-196, 199-205, 208-210 and 211 is 11/13/1998 as stated in previous office action.

***Maintained- Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 193-196, 199-205, 208-210 and 211 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

(i) a non-human host mammal, comprising transgenic germ cells carrying in their genomes a lentiviral vector comprising at least one xenogeneic polynucleotide, so that any progeny animals are transgenic, said non-human host mammal having received an injection in its testis of male germ cells comprising a lentiviral vector comprising at least one xenogeneic polynucleotide encoding a desired product and at least one polynucleotide encoding a genetic selection marker, wherein said xenogeneic polynucleotide is xenogeneic to both said vector and said host, said male germ cells comprising the polynucleotide being isolated or selected from an allogeneic donor male non-human mammal with the aid of the selection marker, and

(ii) a non-human host mammal, or its transgenic progeny, comprising a germ cell carrying in its genome a lentiviral vector comprising at least one xenogeneic polynucleotide, wherein said xenogeneic polynucleotide is xenogeneic to both said vector and said host, said lentiviral vector comprising the polynucleotide having been incorporated into the genome of said germ cell through: (a) obtaining a male germ cell from a allogeneic non human mammal; (b)

transfected the germ cell *in vitro* with a lentiviral vector comprising at least one xenogeneic polynucleotide, wherein said xenogeneic polynucleotide is xenogeneic to both said vector and said host encoding a desired product, and allowing the lentiviral vector and the xenogeneic polynucleotide encoding a desired product to be taken up by, and released into the germ cell, and then injecting cells into testis of the nonhuman host mammal,

does not reasonably provide enablement for injecting or transplanting germ cell from one species of mammal to the testis of different species of mammal or interspecies xenogenic transplant to produce transgenic nonhuman mammal or a progeny thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants arguments filed June 24, 2009 have been fully considered but are not persuasive. Applicants argues that the patent specification fully enables the invention even if reasonable amount of routine experimentation is required in order to practice a claimed invention such experimentation is not undue (see page 6 of the arguments). Applicants assert that claimed invention is not interspecies germ cell translation to produces offspring of a different species. Applicants argue that the male germ cell of the host animal is being transfected with a polynucleotide not normally found in that germ cell. With respect to claim 203, applicants argue that under the *Engel Industries*' test this is all that is required to satisfy the enablement requirement because claim 203 does not distinguish between obtaining the male germ cell from an allogeneic or non-allogeneic nonhuman mammal (see page 7 of the arguments).

In response, it is relevant to point that claim 193 is directed to a non-human host mammal, comprising transgenic germ cells carrying in their genomes a lentiviral vector comprising at least one xenogeneic polynucleotide, said non-human host mammal having received an injection in its testis of male germ cells comprising a lentiviral vector, wherein said male germ cells comprising the polynucleotide being isolated or selected from "a" donor male non-human mammal with the aid of the selection. In the instant case, contrary to applicants' assertion, claim embrace injection of male germ cells comprising a lentiviral vector selected from a donor male non-human mammal. As recited there is no requirement that the male germ cell is isolated from the donor non human mammal of same species of nonhuman host mammal as recited in the preamble. It is emphasized that the claim 193 read on injecting male germ cell

comprising a lentiviral vector comprising xenogeneic polynucleotide encoding a desired product that is not from the same species of non-human host animal. Therefore, breadth of instant claim read on injecting male germ cells from one nonhuman species to another nonhuman host mammal that may be allogeneic or xenogeneic to produce a nonhuman host mammal comprising transgenic germ cell or its progeny. With respect to claim 203, as stated in previous office action, claim embrace any nonhuman host mammal or its transgenic progeny, comprising a germ cell carrying in its genome a lentiviral vector comprising at least one xenogeneic polynucleotide by obtaining a male germ cell from a non human vertebrate and transfecting the germ cell *in vitro* with a lentiviral vector. It is noted that the method steps of claim 203 is inconsistent as it recites obtaining a male germ cell from a nonhuman vertebrate which is broader then nonhuman mammal. It is noted that claim read on genetically modifying male primordial germ cell from a bony fish or amphibian and subsequent implantation of germ cells into the testis of nonhuman mammal, which would not be predictable to produce genetically modified nonhuman host mammal. It is relevant to point that recitation of "a germ cell" from "a non-human vertebrate" in claim 203 step (a) does not link to the nonhuman host mammal of the preamble and therefore claim read on obtaining a male germ cell from any non-human mammal and transfecting with germ cell.

In response to applicants' argument that the enablement requirement is met if the description enables any mode of making and using the claimed invention (*Engel Industries, Inc. v. Lockformer Co*), it is noted that that cited case law is not pertinent to the indicated scope of enablement rejection. Examiner is not raising the issue of disclosure of best mode requirement to make and use the invention. It is emphasized that the breadth of the claims 193-196, 199-205, 208-210 and 211 read on a nonhuman transgenic mammal that involves injecting germ cell from one species of mammal to the testis of same or different species of mammal or interspecies xenogenic transplant to produce transgenic nonhuman mammal or a progeny thereof. While the specification has contemplated that methods of the invention may be used to create any nonhuman transgenic vertebrate of any species, the guidance provided by the specification correlated only to transfection of the testis of a male mouse to generate transgenic mouse comprising lentiviral-comprising GFP (examples 3-9). It is unpredictable if the implantation of a genetically modified male germ cell from one species of nonhuman mammal to another species

involving interspecies xenogenic transplantation using more distantly related species would be successful. Applicants should note that Courts have stated, "It is true, as Genentech argues, that a specification need not disclose what is well known in the art. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986).

However, that general, off-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." (See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)).

The guidance provided in the specification is limited to administering genetic material (GFP) into the testis of a mouse and reverse transcriptase PCR analysis of tissues obtained from the testis show presence of GFP in the injected testes (see example 7-8). The specification also describes the *in vitro* transfection of testicular cells isolated from the testis of a mouse that is then injected into the testis of the mouse via the *vasa efferentia*. It is noted that only two out of three males survived that were bred with normal females resulting in progeny of nonhuman mammal. The specification fails to provide any guidance with respect to the integration of the transgene in the litters (see example 10). The claims as recited are clearly interpreted to read on interspecies xenotransplantation of genetically modified germ cells. One of skill could not rely on the state of the interspecies xenotransplantation art for guidance because the state of the xenotransplantation art is unpredictable with respect to implantation of germ cells into the testes across different animal species as discussed in previous office action (see Griswold et al (Journal of Andrology, 2001, 22, 713-717), Ogawa et al Biol. Reprod. ,1999, ;60(2):515-21) and Dobrinski et al (Mol Reprod Dev. 2000; 57(3):270-9 and Biol Reprod. 1999; 61:1331-1339). The guidance provided by the specification failed to correlate to the donor-host combinations embraced by the claims, particularly in light of the unpredictability of the interspecies xenotransplantation of germ cell art as set forth by the references above. The lack of guidance in

the specification would force the skilled practitioner to guess and try interspecies xenotransplantation of germ cell. Such guessing would require extensive and undue experimentation. Applicant should note that “case law requires that the disclosure of an application shall inform those skilled in the art how to use applicants’ alleged discovery, not to find out how to use it for themselves.” *In re Gardner* 166 USPQ 138 (CCPA) 1970. Given the lack of guidance provided by the specification with respect to donor-host compatibility of xeno transplantation of germ cells it would have required undue experimentation to make and use the invention as claimed for producing transgenic nonhuman mammal without a reasonable expectation of success.

***Maintained -Claim Rejections- 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 185-186, 195-196, 203-205, 208-210 and 211 were rejected under 35 U.S.C. 102(e) as being anticipated by Bryant et al (US Patent 6156952 dated 12/5/2000, effective filing date 4/19/1998, art of record).

Applicants arguments filed June 24, 2009 have been fully considered and are persuasive. Applicants arguments filed June 24, 2009 have been fully considered but are not persuasive. Applicants argue that Bryant et al should be withdrawn because instant application should be afforded priority as November 14, 1997 (see page 8 of the arguments). Applicants argue that Bryant et al are generating transgenic mice by using the classic method of injection of the gene construct into the fertilized egg as opposed to the transduction of male germ cells as required by the claims of the present invention. Applicants assert that the method of Bryant et al is different from that of the present invention and the immediate product of the process is also different, as

the product of the current invention is a transduced male germ cell (see applicants' argument page 9).

In response, it is noted that the effective filing date for instant claims 183-186, 189-196, 199-205, 208-210 and 211 is 11/13/1998 for the reasons discussed earlier in this office action (See priority section). The US 60/065, 825 specification contemplated HIV, but not all lentiviruses. Thus, '825 fail to provide adequate written description for the claimed genus.

Applicants' arguments of classic method of injection of the gene construct into the fertilized egg as opposed to transduction of male germ cells is not persuasive because a progeny nonhuman mammal resulting from the claimed methods would carry polynucleotide sequence in germ as well as somatic cell. Bryant et al teach transgenic non-human animal whose genome comprises lentiviral and at least one additional transgene including human CD4 receptor gene or a gene involved in a disease (see col. 4, lines 8-20, 30-40 and 58-65). In addition, Bryant et al also disclose a method of producing the transgenic nonhuman animal described identification and quantitation of transgene in the founder animals and their progeny (see col. 14 and 15). Brynat et al contemplate transgenic animal of the invention includes mouse, rat, rabbit, pigs, baboons and monkeys (see col. 10, lines 48-52). The progeny transgenic nonhuman animal disclosed by Bryant et al and those embraced by the instant claims appear to be structurally same. With respect to applicants' argument that method of Bryant et al is different from that of the present invention, it is noted that the resulting progeny of nonhuman mammal disclosed by Bryant would carry polynucleotide sequence in germ as well as somatic cell and therefore structurally similar to claimed product. Where the claimed and prior art products are identical or substantially identical in structure or composition, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. Furthermore, MPEP § 2113 states, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The

patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Accordingly, Bryant et al anticipates claims 185-186, 195-196, 203-205, 208-210 and 211.

### ***Maintained-Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 183-186, 189-196, 199-205, 208-210 and 211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brinster et al (US Patent 5,858,354, dated 1/12/1999, filed on 11/21/1994, art of record) and Naldini et al., (Science, 1996, 272: 263-267, IDS).

The claims are directed to a non human mammal comprising transgenic germ cell and a progeny thereof. Claims are also directed to a nonhuman mammal comprising transgenic germ cell by obtaining a donor or native male germ cell from a non-human mammal and transfecting the germ cell in vitro with at least one polynucleotide encoding a gene product and allowing the polynucleotide to be taken up and released into the germ cell.

Claim interpretation: Instant claims are product by process claims (see MPEP § 2113). Claim 183 is interpreted to embrace a nonhuman mammal comprising genetically modified male germ cells. It is noted that while base claim only requires germ cells be transduced with the polynucleotide sequence, however, resulting progeny set forth in claims 185 would contain transgene in somatic as well as germ cell. Claim 193 is interpreted to embrace a non human host mammal comprising transgenic germ cell, wherein male germ cell comprising the polynucleotide being isolated or selected from a donor male non human mammal. Thus, breadth of these claims embraces genetically modifying germ cell of a donor male and then transplanting germ cell into host male animal. Claim 203 is interpreted to embrace a nonhuman host mammal that is obtained

by obtaining germ cell from any nonhuman mammal and then transfecting the germ cell *in vitro* with lentiviral vector comprising polynucleotide such that desired product that is taken up and released into the germ cell. The *in vitro* transfected germ cell upon transplantation into the host mammal is interpreted as native to the host mammal. It is noted that method steps recited in the claims do not require *in vitro* transfected germ cell to be same as native germ cell. Therefore, a male germ cell from non human mammal that is transfected *in vitro* with the vector upon transplantation into the host mammal is interpreted as native germ cell.

Regarding a non human mammal comprising transgenic germ cell, Brinster et al. teach introduction of the transgene construct to a sperm that could be introduced to the seminiferous tubules of a host male animal (Brinster et al., col., 13, lines 14-17). Brinster et al. also teach that male germ cells are cultured at around or below the body temperature (32°C) because of their sensitivity to high temperatures (Brinster et al., col. 6, lines 30-32) and same could be used for transfection. Practicing the methods claimed by Brinster *et al.* result in a transgenic animal comprising germ cells that have been genetically modified with a transgene meeting the limitation of base claim 183, 193 and 203.

Brinster et al. teach that the heterologous DNA sequence can be transferred into the germ or other primitive cells by a viral vector, such as a retroviral vector or an adenoviral vector (Brinster et al., col., 7, line 66 to col. 8, line 32). Brinster et al. teach a method of *in vitro* transfection primitive germ cells (Brinster et al., col. 5-7, especially, col. 6, line 1, 30, col. 7, lines 36-45) with a heterologous DNA sequence encoding a gene of interest (Brinster et al., col. 8, lines 33-49). Brinster et al. further teach that the DNA sequence may be obtained from a source of the same species or from different species (Brinster et al., col. 8, lines 50-55). Brinster et al. further teach that such methods may be applicable to any species of animals, in which the male has testes including mice, rat, swine and other farm animals (Brinster et al., col. 10, and lines 27-43). It is also disclosed that the primitive cells may also be native cells possessing naturally or artificially induced mutation (see col. 7, line 42). Brinster et al. further teach that cell comprising the transgene construct can be tracked by including a nucleic acid sequence encoding a genetic marker (e.g. lacZ) operably linked to a sperm-specific promoter (Brinster et al., col., 11, line 58 to col. 12, line 19).

With respect to claims drawn to progeny non human mammal, Brinster et al. teach that progeny mice comprising the transgene were obtained following treatment of primitive cells with a transgene (Brinster et al., col., 18, lines 57-65, col., 19, lines 4-6).

While Brinster et al. teach that a wide variety of viral vectors that could be used to produce a nonhuman mammal comprising transgenic germ cell or a progeny thereof, they do not specifically teach use of lentiviral vectors.

However prior to filing of instant application, lentiviral vectors were known to be more efficient than other vectors in transducing cells and provided a more sustained level of expression. Naldini et al. cure the deficiency of Brinster et al by teaching lentiviral vectors that could be used to deliver gene of interest to dividing as well as non dividing cell more efficiently as compared to other viral vectors (see abstract and entire article).

At the time of filing of this application it would have been obvious to one of ordinary skill in the art to modify the method of producing a non human mammal comprising transgenic germ cell or a progeny thereof disclosed by Brinster et al. by substituting adeno or retroviral vector with equivalent lentiviral vector with a reasonable expectation of success of achieving predictable result. One of ordinary skill in the art would be substitute one viral vector as disclosed by Brinster with another such as lentiviral vector as disclosed by Naldini as a matter of design choice to improve transfection efficiency. Given that Brinster et al. provide guidance that a wide variety of viral vectors can be used for delivery of a gene of interest, using another vector, i.e., a lentiviral vector, is a matter of design choice and an artisan would have been as likely to use a lentiviral vector as any other viral vector in a method of introducing a transgene to a germ cell to produce nonhuman mammal comprising transgenic germ cell and transgenic progeny therefrom. One of skill in the art would have had a reasonable expectation of success in combining the teachings of Brinster with those of Naldini because it was routine in the art at the time of filing to substitute the one viral vector disclosed by Brinster with another to improve transduction efficiency to produce transgenic nonhuman mammal.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

***Response to the arguments***

Applicants disagree with the rejection of claims over Brinster et al and Naldini et al, arguing that Brinster et al do not disclose lentiviral vectors as required by the claims. Applicants further argue that in an attempt to address this deficiency, the Examiner cites Naldini. While Naldini does describe lentiviral vectors, it does not provide any suggestion or teaching of the use of lentiviral vectors required by applicant's claims. Applicants argue that there is no suggestion of the lentiviral vector of Naldini being suitable for transfection of male germ cells. Applicants assert that combination of references teaches away from such use of lentiviral vectors because Brinster describes other vectors that do work. Given Brinster's description of other vectors that do work, there is nothing in either Naldini or Brinster that would motivate one of ordinary skill to use lentiviral vectors that may not work. Applicants' arguments have been fully considered, but are not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants have further engaged in selective reading of the teachings of Brinster et al. to formulate the grounds for teaching away.

As previously indicated, Brinster et al. in describing teach that the heterologous DNA sequence can be transferred into the germ or other primitive cells by any viral vector, such as a retroviral vector or an adenoviral vector (Brinster et al., col., 7, line 66 to col. 8, line 32). It is further noted that the disclosure of Brinster et al is not limited to any specific viral vector, but include any viral vector or particle derived form naturally occurring viruses that have been genetically altered to render them replication defective and to express recombinant gene (see col. 8, line 27-31). Further, applicants on record agree that lentiviral vectors are a type of retrovirus that can infect both dividing and non-dividing cells because their pre-integration complex (virus "shell") can get through the intact membrane of the nucleus of the target cell (page 2 last para. of the argument). Thus, Brinster et al. teach transfecting germ cell using variety of viral vector including retroviral vector, however, differ from claimed invention by not explicitly disclosing that the retroviral vector is lentiviral vector. However, such is disclosed by Naldini et al who reported lentiviral vectors could be used to deliver gene of interest to dividing as well as non

dividing cell more efficiently as compared to other viral vectors. To the extent that Naldini et al. describe the transfection of dividing and non dividing cell by lentiviral vector, the rejection is applicable to the instant case. In absence of any requirement for any specific phenotype of the resulting transgenic nonhuman mammal, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teachings of Brinster et al., and Naldini et al. to infect germ cells using lentiviral vector as a matter of design choice, in order to produce nonhuman transgenic mammal and progeny thereof, as instantly claimed, with a reasonable expectation of success, at the time of the instant invention. Said design choice amounting to combining prior art elements according to known methods to yield predictable results. It should be noted that the *KSR* case forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obviousness See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

***Conclusion***

No Claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/  
Primary Examiner, Art Unit 1632

Anoop Singh  
AU 1632